

HCFA had rescinded or revoked its approval, or discontinue the action within a reasonable “wind down” period, as determined by HCFA.

[63 FR 1657, Jan. 9, 1998]

§ 411.384 Disclosing advisory opinions and supporting information.

(a) Advisory opinions that HCFA issues and releases in accordance with the procedures set forth in this subpart are available to the public.

(b) Promptly after HCFA issues an advisory opinion and releases it to the requestor, HCFA makes available a copy of the advisory opinion for public inspection during its normal hours of operation and on the DHHS/HCFA web site.

(c) Any predecisional document, or part of such predecisional document, that is prepared by HCFA, the Department of Justice, or any other Department or agency of the United States in connection with an advisory opinion request under the procedures set forth in this part is exempt from disclosure under 5 U.S.C. 552, and will not be made publicly available.

(d) Documents submitted by the requestor to HCFA in connection with a request for an advisory opinion are available to the public to the extent they are required to be made available by 5 U.S.C. 552, through procedures set forth in 45 CFR part 5.

(e) Nothing in this section limits HCFA’s obligation, under applicable laws, to publicly disclose the identity of the requesting party or parties, and the nature of the action HCFA has taken in response to the request.

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§ 411.386 HCFA’s advisory opinions as exclusive.

The procedures described in this subpart constitute the only method by which any individuals or entities can obtain a binding advisory opinion on the subject of a physician’s referrals, as described in § 411.370. HCFA has not and does not issue a binding advisory opinion on the subject matter in § 411.370, in either oral or written form, except through written opinions it issues in accordance with this subpart.

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§ 411.387 Parties affected by advisory opinions.

An advisory opinion issued by HCFA does not apply in any way to any individual or entity that does not join in the request for the opinion. Individuals or entities other than the requestor(s) may not rely on an advisory opinion.

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§ 411.388 When advisory opinions are not admissible evidence.

The failure of a party to seek or to receive an advisory opinion may not be introduced into evidence to prove that the party either intended or did not intend to violate the provisions of sections 1128, 1128A or 1128B of the Act.

[63 FR 1658, Jan. 9, 1998]

§ 411.389 Range of the advisory opinion.

(a) An advisory opinion states only HCFA’s opinion regarding the subject matter of the request. If the subject of an advisory opinion is an arrangement that must be approved by or is regulated by any other agency, HCFA’s advisory opinion cannot be read to indicate HCFA’s views on the legal or factual issues that may be raised before that agency.

(b) An advisory opinion that HCFA issues under this part does not bind or obligate any agency other than the Department. It does not affect the requestor’s, or anyone else’s, obligations to any other agency, or under any statutory or regulatory provision other than that which is the specific subject matter of the advisory opinion.

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Subpart K—Payment for Certain Excluded Services

§ 411.400 Payment for custodial care and services not reasonable and necessary.

(a) *Conditions for payment.* Notwithstanding the exclusions set forth in § 411.15 (g) and (k). Medicare pays for “custodial care” and “services not reasonable and necessary” if the following conditions are met: